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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,114	07/18/2003	Yerramilli V.S.N. Murthy	051091-2001	4452

23838 7590 10/23/2006

KENYON & KENYON LLP
1500 K STREET N.W.
SUITE 700
WASHINGTON, DC 20005

EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/623,114	MURTHY ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *11-15, 18-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,16 and 17* is/are rejected.

7)☒ Claim(s) *16, 17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 9/13/06; 2/8/05; 1/24/04; 1/6/04;
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I (claims 1-10 and 16-17) drawn to a composition of a prodrug of florfenicol and a pharmaceutically acceptable carrier, provided in an injectable composition and a compound of florfenicol, classified in class 514, subclass 618; class 465, subclass 212 is acknowledged. The traversal is on the ground(s) that Group II can be examined together with claims of elected Group I without requiring no additional search by the Examiner and would not impose an undue burden because the inventions of Group I and II represent closely related subject matter. This is not found persuasive because each of the inventions of Group I and group II are distinct, each from the other because the process as claimed can be used in a materially different process of using that product since the product can be use as an antiseptic in vitro non-human use without requiring vivo administration comprising conversion. Therefore, a serious burden would place on the examiner to perform required search, particularly, non-patent literature search involving both unrelated process and mechanisms of vitro and vivo comprising different pathways employing the claimed composition. Therefore, the restriction requirement made on the last Office Action is proper and made final.

Claims 1-10, 16 and 17 are being examined and claims 11-15 and 18-24 are withdrawn from consideration because they are non-elected invention.

Claim Objections

Claims 16 and 17 are objected to because of the following informalities: Claims 16 and 17 depend from withdrawn claim 15. To accelerate the prosecution of instant Application, claims 16 and 17 are examined as it they depend from claim 10.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Boojamra et al. (US 2006/0014743A1) of record.

Boojamra et al. teach that a novel florfenicol compound, a prodrug thereof or a physiologically acceptable salts of either the compound or its prodrug administered in pharmaceutical composition. (abstract, [0083]). Boojamra et al. teach that the composition can be administered including oral, rectal, intramuscular, subcutaneous and intravenous and the preferred routes of administration is parenteral. ([0085]). Boojamra et al. teach that the administration refers to the delivery of a compound, salt or prodrug of the florfenicol compound. (abstract, [0084]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-10 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boojamra et al. (US 2006/0014743A1) of record as applied to claim 1 above, and

further in view of LaColla et al. (U.S.Patent No. 6,710,068 B2) and Schoenleber et al. (U.S.Patent No. 5,158,948).

Boojamra et al. as applied as before and additional teaching as follows:

Boojamra et al. teach the effective amount of florfenicol prodrug is well within the capability of those skilled in the art and the dosage may vary depending upon the dosage form and route of administration. ([0099], [0101]). In general, however, the preferred dosage range form systemic delivery of the compound is about 1 to about 100mg/kg. ([0101]).

Boojamra et al. do not teach the esterifed form and the specified concentrations of florfenicol.

LaColla et al. teach that the term "pharmaceutically acceptable prodrug" is described as any pharmaceutically acceptable form (such as an ester and salt of an ester) of a compound that upon administration to a patient provides the active compound. (column 29, lines 9-40).

Schoenleber et al. teach the examples of esters useful as prodrug for compound containing phenol groups include, esters such as acetates, propionates and n-butryates. (column 11, lines 8-27).

It would have been obvious to one of ordinary skill in the art to employ esterifed form of florfenicol in formulating florfenicol prodrug of Boojamra et al. because Boojamra et al. teach that any pharmaceutically acceptable prodrug of florfenicol can be employed and because an ester and salt of an ester is well known pharmaceutically accepted form of prodrug as taught by LaColla et al. One of ordinary skill in the art would have been

motivated to employ esters such as acetates, propionates and n-butryates in Boojamra et al's florfenicol prodrug in order to successfully formulate florfenicol prodrug that is pharmaceutical acceptable and well-known to deliver active florfenicol in vivo, upon administration to a patient. To optimize the amount of concentration of the active agent to be used for the preferred parenteral route of florfenicol prodrug taught by Boojamra et al. is obvious because Boojamra et al. teach the effective amount of florfenicol prodrug is well within the capability of those skilled in the art and the dosage may vary depending upon the dosage form and route of administration. One of ordinary skill in the art would be motivated to determine the desired concentration in order to successfully deliver florfenicol prodrug according to the preferred parenteral administration.

Claims 8-10 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Camaggi et al. (U.S.Patent No. 5,336,664).

Camaggi et al. teach that florfenicol compound including florfenicol propionate is useful in the composition for agricultural use as herbicides in the defense of useful crops from weeds. (abstract, columns1-4, particularly column 4, lines 47-68). Camaggi et al. teach that the composition can be formulated with the carrier such as water (pharmaceutically acceptable carrier). (column 14, lines 61-66).

Camaggi et al. do not expressly illustrate florfenicol propionate compound and useful for a pharmaceutical composition for administration to a mammal.

It would have been obvious to one of ordinary skill in the art to prepare florfenicol compound including florfenicol propionate because Camaggi et al. teach florfenicol compound in general are useful as an agriculture composition and because Camaggi et al. teach that florfenicol propionate can be prepared from florfenicol compounds therein. One would have been motivated to prepare florfenicol compounds including florfenicol propionate in order to achieve an expected agricultural benefit in crops.

With regard to intended use for administration to a mammal set forth in claim 9, it is noted that that intended use does not represent a patentable limitation in composition claims because such fails to impart any physical limitation to the same composition taught by prior art. With regard to claims drawn to the term "pharmaceutical" in preamble set forth in claims 9 and 10, it is well recognized in the patent law that for composition claim is that portion stated after the term "comprising" therefore applicant's composition claims for a "pharmaceutical composition" set forth in claims 9 and 10 read upon the composition of above reference.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Kim
Patent Examiner
Art Unit 1617

Jmk
September 27, 2006